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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/791,198	03/02/2004	Kevin E. Henegar	00509.US1 DV1	1977
25533	7590	09/15/2004	EXAMINER	
PHARMACIA & UPJOHN 301 HENRIETTA ST 0228-32-LAW KALAMAZOO, MI 49007			AULAKH, CHARANJIT	
			ART UNIT	PAPER NUMBER
			1625	

DATE MAILED: 09/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/791,198

Applicant(s)

HENEGAR, KEVIN E.

Examiner

Charanjit S. Aulakh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 11-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

### **DETAILED ACTION**

1. According to a preliminary amendment filed on March 2, 2004, the applicants have canceled claims 1-10 and furthermore, have amended claims 11-14.
2. Claims 11-14 are now pending in the application.

### ***Priority***

3. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 11-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In independent claim 11, the term ---total--- is indefinite since its meaning or actual intent is not clear.

In independent claim 11, the term ---detectable amount--- is indefinite since its meaning is not clear. This term is usually used for radioactive compounds. Also, it is not clear how this amount is being detected? What is the benefit of adding this amount to the composition since utility of the composition is solely based on the therapeutic effects of irinotecan alone? Does it enhance the efficacy or reduces side effects of irinotecan?

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Toutain (U.S. Patent no. 6,476,043).

Toutain discloses use of camptothecin derivatives, with reduced gastrointestinal toxicity.

The medicinal product or pharmaceutical composition disclosed by Toutain ( see claims

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1-5 ) meets all the limitations except that it does not mention detectable amount of 4-amino-3-propionylphenyl-1,4'-bipiperidine-1'-carboxylate in the composition. However, Toutain teaches the utility of irinotecan for treating cancer ( see claims 6-12 ). It is also well established in the prior art to combine the main therapeutic compound with other compounds in order to produce a synergistic effect or reduce it's side effects as combined by Toutain ( see composition claims 1-5 as well as method claims 6-12 ). In the instant composition, the therapeutic effect is solely due to irinotecan and therefore, in absence of some unexpected results of superior activity or reduced side effects by the instant combination over the prior art known composition comprising irinotecan, it would have been obvious to one skilled in the art to prepare the instant composition without losing its therapeutic utility for treating cancer.

9. Claims 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bissery (U.S. Patent no. 6,545,010).

Bissery discloses composition comprising camptothecin or camptothecin derivative and a platin derivative for the treatment of cancer. The pharmaceutical composition disclosed by Bissery ( see claim 16 ) meets all the limitations except that it does not mention detectable amount of 4-amino-3-propionylphenyl-1,4'-bipiperidine-1'-carboxylate in the composition. However, Bissery teaches the utility of irinotecan for treating cancer ( see claims 1-15 ). It is also well established in the prior art to combine the main therapeutic compound with other compounds in order to produce a synergistic effect or reduce it's side effects as combined by Bissery ( see composition claim 16 as well as method claims 1-15 ). In the instant composition, the therapeutic effect is solely


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due to irinotecan and therefore, in absence of some unexpected results of superior activity or reduced side effects by the instant combination over the prior art known composition comprising irinotecan, it would have been obvious to one skilled in the art to prepare the instant composition without losing its therapeutic utility for treating cancer.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charanjit S. Aulakh whose telephone number is (571)272-0678. The examiner can normally be reached on Monday through Friday, 8:30 A.M. to 5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571)272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Charanjit S. Aulakh  
Primary Examiner  
Art Unit 1625